



Increasing biomedical research and improving the health of the people of Indiana and beyond.



A Letter from Anantha Shekhar, M.D., Ph.D., Director of the Indiana CTSI

We now are seven years into the development of the Indiana Clinical and Translational Sciences Institute, and more importantly, into the statewide collaborative laboratory of researchers, clinicians, businesses and communities that make this organization a model for such programs around the country.

You're holding a snapshot report of a few of our success stories and the plans we have for creating more successes in the future. A more substantial report of these stories and others can be found on the Indiana CTSI Hub (www.indianactsi.org).

We've had no bigger success story recently than our renewed funding in 2013 of \$30 million. With Indiana CTSI 1.0 we built a foundation that brought together academic researchers across the state, many for the first time. Now, with Indiana CTSI 2.0 we are:

- Working to fundamentally change the environment for clinical and translational research.
- Extending and strengthening our efforts in career development, education and research training to create the next generation of clinical researchers.
- Leveraging the strengths of public and private partnerships – in Indiana and well beyond the state boundaries.

We have highlighted a few examples of that work in this document.

Whether you are a scientist, a student, a business veteran, a startup entrepreneur, a community leader or a patient, there is a role for you as we work together; as we say in our mission statement, we can all collaborate to "conduct the highest-quality research dedicated to improving human health across Indiana and beyond."

SUCCESS STORIES

Matthias Clauss and the PRMC

The peer review and mentoring committee (PRMC) program has been building momentum at the IU School of Medicine since its start in 2014, with one of the early beneficiaries being Matthias Clauss, Ph.D., associate research professor of cellular and integrative physiology.

Dr. Clauss met with the cardiovascular PRMC regarding a study that proposed to look at the process in which Nef – a protein that is encoded by the HIV virus – inserts itself into the endothelial cells lining blood vessels, leading to cardiovascular problems. The committee granted Dr. Clauss and his colleagues \$14,600 to create a mouse model and collect preliminary data.

"The results were instrumental in getting a fundable score from the NIH," said Dr. Clauss, a score that resulted in a four-year, \$1.8 million award in 2015 from the National Heart Lung and Blood Institute.

Diabetic wound healing

Research at the University of Notre Dame by Mayland Chang, research professor, and Shahriar Mobashery, Navari Family Professor in Life Sciences, examining the molecular basis of disease may result in the first pharmacological intervention to treat slow-healing diabetic wounds.

The Department of Chemistry and Biochemistry investigators studied matrix metalloproteinases, enzymes with roles in extracellular matrix component degradation and cell death. Their role in diabetic wound healing was unknown.

The researchers identified two MMPs of interest – MMP-8 and MMP-9 – and tested them in mouse models. A core grant of \$10,000 from the Indiana CTSI covered the expenses of obtaining mice used to determine how to mimic diabetic wounds.

Drs. Chang and Mobashery reported in the journal ACS Chemical Biology in 2014 that treating the wounds with a compound that inhibits MMP-9 resulted in speedier wound healing, regrowth of skin and slower cell death.

SpeechVive helps Parkinson's patients

A bit of funding and good advice can go a long way, as in the case of SpeechVive Inc., producer of a device that can improve the quality of life of people with Parkinson's disease.

People with Parkinson's disease commonly have voice-related symptoms, affecting how loudly, or how clearly, they can speak.

In 2010 an Indiana CTSI project development team provided \$10,000 to Jessica Huber. **Purdue University** professor of speech, language and hearing sciences, to develop a prototype device meant to reduce speech impairments that



commonly affect patients with Parkinson's.

The SpeechVive product is a smart earpiece that detects when the wearer is speaking and delivers a background sound that results in the wearer speaking more loudly and clearly.

The project attracted \$2.25 million from the National Institutes of Health, \$1 million in product development funding from a Purdue Research Foundation program, then last year, \$700,000 from the Ambassador Enterprises to enable the SpeechVive device to go into production.

CHANGING THE RESEARCH ENVIRONMENT

Clinical Trials Office created as single entry point for IU clinical trials

To eliminate barriers and promote high-quality research, University Clinical Affairs has created the Clinical Trials Office as a single entry point for all

Indiana University clinical trials. The services in this office include contracting and Forte's OnCore Clinical Trial Management system.

To shorten the time needed to initiate and execute contracts, the Indiana CTSI adopted Six Sigma methods to evaluate the clinical research process at IU and IU Health. This enabled the Indiana CTSI to identify steps that generate backlogs and excessive processing time. The Clinical Trials Office is addressing the opportunities to eliminate unneeded steps and to re-engineer processes to increase efficiency without sacrificing accountability.

The Clinical Trials Office will provide assistance to investigators in all health sciences schools on the IUPUI campus. For more information contact Director Ken Carlson at kcarlso@iu.edu or 317-278-2548.

Bill Barnett named CRIO for Indiana CTSI and Regenstrief Institute

The Indiana CTSI and the Regenstrief Institute announced a new joint chief research informatics officer position in June 2015 and appointed William K. Barnett, Ph.D., to the post. With the goal of integrating and advancing the two organizations' research informatics efforts, Barnett will lead the development of information technology strategies to support research and the design of infrastructures for the acquisition, management and analysis of research data.



The new position will have a dual mission: to provide information technology and informatics services for health sciences research and to develop and implement novel information technology and informatics solutions for health care issues.

"Establishing this office cements an important, and we think unique, partnership

between the Indiana CTSI, with its statewide research collaborations, and the applied informatics expertise of the Regenstrief Institute, and will provide a tremendous resource to researchers across Indiana," said Anantha Shekhar, M.D., Ph.D., director of the Indiana CTSI and executive associate dean for research affairs.

Dr. Barnett will continue to serve as associate director of the IU Center for Advanced Cybersecurity Research.

CHEP encourages a patientcentered approach to research

The Indiana CTSI's Community Health Engagement Program (CHEP) believes patient engagement and design research methods can change the clinical and translational research environment.

CHEP director Sarah Wiehe, M.D., M.P.H., along with her interdisciplinary team, including communication design experts, have put this idea into action.

Wiehe's team – the Patient Engagement Core (PEC) – uses a combination of patient engagement and design methodology to create solutions that address study-related issues.



Recently the PEC assisted Kenneth Levy, Ph.D., adjunct associate professor of medicine, in his study on pharmacogenetics, which studies how genetics impact patient response to medication. The goal? To recruit more patients to take part in the study. The problem? The patients didn't understand pharmacogenetics.

The PEC team led 10 participants through a series of activities to first uncover barriers to recruitment, and then to frame pharmacogenetics from a patient's perspective.

The result? Patient-accessible definitions like, "Pharmacogenetics is kind of like being able to try on clothes before you buy them instead of crossing your fingers and hoping they fit."

Since its start, the PEC has worked with 17 investigators and has 15 active projects. For more information, contact chep@iupui.edu.

LEVERAGING PUBLIC - PRIVATE PARTNERSHIPS

Improving the process of translation through public-private partnerships

Need to find an IU scientist? The Industry Collaboration Portal is a "one-stop-shopping" interface between business and the resources of the IU School of Medicine. The ICP, led by director Jaipal Singh, Ph.D., and the portal's Industry Collaboration Team of faculty experts will direct inquiries to appropriate investigators.

Need a place to develop and commercialize vour inventions? The new Indiana Center for Biomedical Innovation is creating a platform for technology development by providing fully equipped laboratory space and an animal facility to university faculty and Indiana innovators. ICBI will focus on providing research space, expert advisors, funding and an entrepreneurial

environment for technology development. The ICBI is located in the former Methodist Research Institute space in IU Health Methodist Hospital.

Need some good business advice? The Program to Connect Relevant Industry Mentors to Entrepreneur-Researchers – PRIMER – is a collaboration between the Indiana Health Industry Forum and university technology transfer offices to provide mentoring advice from experienced entrepreneurs to startups built on academic intellectual property.

Need some SPARK? The Indiana CTSI Industry Collaboration Portal is working with Stanford University's SPARK, a successful university-industry partnership that provides education, mentorship and funding to help startup companies bridge the gap from bench to bedside.

For more information on these programs visit www.indianactsi.org.

FUNDING OPPORTUNITIES

Project Development Help

Facilitates translational research projects for individual and/or team investigators and provides resources, services and training needed for external submissions. Eligibility: Researchers in translational and clinical research at all Indiana CTSI institutions. For more information, visit www.indianactsi.org/programs/pdt

Pilot Project Funding

The Indiana CTSI provides funding through its member institutions and public/private partnerships for new research projects, collaborative grants, core services and training funds.

Eligibility: Faculty from all participating institutions. For more information, visit www.indianactsi.org/pilotfund

EDUCATION OPPORTUNITIES

The Indiana CTSI's education opportunities facilitate the next generation of researchers, beginning with high school students.

- Summer internship programs (High school, undergraduates, medical students)
- Degree/Certificate Programs:
 - MS/Certificate in Clinical Research
 - MS/Certificate in Translational Research
 - Ph.D. Minor in Translational Science
 - MD/MS Program
 - Certificate in Innovation and Implementation Science
- Pre- and Postdoctoral training
- Independent Investigator Incubator (I³)
- Pharmacometric Modeling Training Program
- Research Coordinator Training

Learn more about these opportunities at www.indianactsi.org.

RESOURCES

Research Navigators

Scientists by training, research navigators are the single point of entry to the Indiana CTSI. Navigators help faculty and investigators engage with many Indiana CTSI services, including facilities, research laboratories, seed grants, patient recruitment, clinical research facilities and more. To connect with a navigator, email navigate@indianactsi.org

IU Bloomington Navigator Yvonne Lai, Ph.D. 812-856-2524

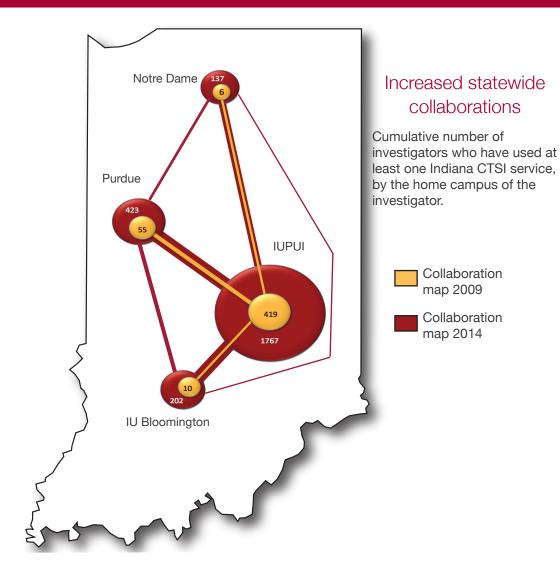
Purdue Navigator Tommy Sors, Ph.D. 765-494-1678

Notre Dame Navigator Bruce Melancon, Ph.D. 574-631-4513

IU School of Medicine, IUPUI Navigator Tammy Sajdyk, Ph.D., MS 317-278-7488



ABOUT INDIANA CTSI





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